



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/763,793

02/27/2001

Hiromasa Miyaji

766.46

3687

5514

7590

07/03/2008

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

SHAFFER, SHULAMITH H

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/763,793	Applicant(s) MIYAJI ET AL.	
	Examiner SHULAMITH H. SHAFER	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 02 April 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1-12 and 46-48.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Lorraine Spector/ Ph.D.
Primary Examiner, Art Unit 1647

Amendment to claims filed on 3/27/08 has been entered. Claims 2 and 12 have been amended; claims 29 and 42 have been cancelled. However, the amendments do not place the claims in condition for allowance.

The amendment to the claims overcome the rejection of claims 2, 5, 6, 8-12, 29, 42, 46 and 48 under 35 USC 112, 1st paragraph (scope of enablement) and written description.

The rejections of the claims under 35 USC 101 and 112 (utility and enablement) is maintained for reasons of record and for reasons set forth below.

Applicant traverses this rejection in reply of 27 March 2008. The reasons for the traversal are:

The polypeptide of SEQ ID NO:1 is a member of the nucleoside transporter family; response to this argument is of record and presented in previous office action (2 October 2007).

Reference submitted by applicant, Crimi et al. (1988, Allergy 43:179-183) teaches that dipyridamole, which inhibits uptake of adenosine, enhances bronchospasm. Applicant asserts that bronchospasm is suppressed by accelerating uptake of adenosine; the polypeptide of SEQ ID NO:1, which has the activity of promoting adenosine uptake is useful in treatment of bronchospasm associated with asthma, "therefore when a DNA encoding SEQ ID NO:1 is expressed in lung of asthmatic patients, bronchospasm in the patient is treated" (response of 27 March 2008, page 8, 1st paragraph)..

Applicant's arguments have been considered but has not been found persuasive for reasons of record and for reasons set forth below.

The reference cited by applicant teaches that inhaled adenosine cause bronchoconstriction (bronchospasm); dipyridamole inhalation increased adenosine hyperresponsiveness (page 181, 1st column, 2nd paragraph). The reference thus teaches "adenosine induced bronchoconstriction in asthmatic patients" (page 182, 1st column, 1st paragraph). "Dipyridamole inhalation increased airway responsiveness to adenosine" (page 182, 1st column, 2nd paragraph). Thus, contrary to applicant's assertion, the reference teaches increased adenosine uptake would lead to increased bronchospasm, and would not be effective as a treatment of asthma.

Therefore, a well-established utility for the polypeptide of SEQ ID NO:1 has not been established.

It is noted that a nucleic acid, SEQ ID NO:78 that is 99.2% identical to nucleic acid of SEQ ID NO:2 is taught by Baker et al (US 7,355,000, priority claimed provisional application 60/106,902, filed 3 November 2008) (See results in SCORE).

SHS